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10/719,534	11/21/2003	Anthony H. Cincotta	02591/100B206-US3	3460
7278 7590 12/27/2006 DARBY & DARBY P.C. P. O. BOX 5257			EXAMINER	
			AEDER, SEAN E	
NEW YORK, NY 10150-5257			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTOR	LY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)					
Office Assistant Occurrence	10/719,534	CINCOTTA ET AL.					
Office Action Summary	Examiner	Art Unit					
	Sean E. Aeder, Ph.D.	1642					
The MAILING DATE of this communication appropried for Reply	•	·					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 27 No	ovember 2006.						
· <u> </u>							
3) Since this application is in condition for allowan							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-22</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-22</u> is/are rejected.	6)⊠ Claim(s) <u>1-22</u> is/are rejected.						
7) Claim(s) <u>20</u> is/are objected to.	alas Para and an analas						
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
·							
Attachment(s)							
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.							
3) Notice of Information Disclosure Statement(s) (PTO/SB/08)							
Paper No(s)/Mail Date <u>3/12/04</u> . 6) Other:							

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Detailed Action

The Election filed 11/27/06 in response to the Office Action of 5/26/06 is acknowledged and has been entered. Applicant elected the prolactin enhancer "domperidone" and the photosensitizer "5-ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride" (2-iodoethyl-NBS) with traverse.

The traversal is on the ground(s) that Applicant asserts that the prolacting enhancers recited in the claims share a common utility since Applicant asserts that all the prolactin enhancers recited in the claims increase the levels of prolactin that circulate in the blood of a mammal to which they are administered. Applicant further argues that the photosensitizers recited in the claims share a common utility and share substantial structural features being essential to said utility. Applicant further states the claims are drawn to an invention encompassing a method for arresting the growth of or eradicating tumors in a mammal bearing one or more tumors by combined treatment with prolactin rhythm re-setting therapy and photodynamic therapy. Applicant states that unity of invention is found in the use of the combination of treatment with a prolacting enhancer and a photodynamic therapy agent. Applicant concludes that it is in error for the Examiner to require election of species because the present claims include unity of invention. In view of the arguments regarding photosensitizers, Examiner has rejoined the photosensitizers recited in the pending claims. In view of an overlapping search, the unelected prolactin enhancers have been rejoined. Upon rejoining the photosensitizers and the prolactin enhancers recited in the claims, the restriction requirement is deemed to be proper and is therefore made FINAL.

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Claims 1-22 are pending and are currently under consideration.

Double Patenting Objection

Claim 20 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 15. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-3, 6, 10, 15, 20, 21, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 8, 13, and 19 of U.S. Patent No. 5,792,748 in view of Werning et al (Arch. Ontolaryngol. Head Neck Surg., 7/95, 121:783-789) and Cincotta et al (Cancer Research, 1994, 54:1249-1258) as evidenced by Molitch (Endocrinol. Metab. Clin. North Am., 1992, 21(4) abstract). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 1 is broadly drawn to a method for arresting growth of or eradicating tumors in a mammal comprising the steps of: (a) comparing the daily plasma prolactin profile of said tumor bearing mammal to a normal daily prolactin profile for healthy mammals of the same species and sex, (b) adjusting the daily plasma prolactin profile of said tumor bearing mammal by administering a prolactin enhancer at appropriate time intervals of day such that the adjusted daily plasma prolactin profile of said tumor bearing mammal conforms to or approaches the normal daily plasma prolactin profile for healthy members of the same species and sex of said mammal; (c) contacting the cells of said tumor with a benzophenoxazine-analog photosensitizer having phototoxicity against tumor cells, and (d) exposing said contacted tumor cells to light. Claim 2 is drawn to the method of claim 1, wherein said tumor bearing mammal is a human. Claim 3 is drawn to the method of claim 2 wherein said prolactin enhancer is a member selected from the group consisting of prolactin, melatonin, metoclopramide, domperidone, 5-hydroxytryptophan, and pharmaceutically acceptable salts thereof. Claim 6 is drawn to the method of claim 3 wherein said prolactin enhancer is prolactin.

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Claim 10 is drawn to the method of claim 2 wherein said photosensitizer is selected from the group consisting of porphyrin dyes, phthalocyanine dyes, cyanine dyes, benzophenoxazine analogs, and pharmaceutically acceptable salts thereof. Claim 15 is drawn to the method of claim 10, wherein said benzophenoxazine analog is a member selected from the group consisting of 5-ethylamino-9-diethylamino-2iodobenzo[a]phenothiazinium chloride and 5-ethylamino-9-diethylaminobenzo[a]phenothiazinium chloride. Claim 20 is drawn to the method of claims 10 wherein said benzophenoxazine analog is drawn to the method of claim 14 wherein said benzophenoxazine analog is a member selected from the group consisting of 5ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride and 5-ethylamino-9diethylamino-benzo[a]phenothiazinium chloride. Claim 21 is drawn to the method of claim 1, wherein administering the prolactin enhancer adjusts the daily prolactin peak of the tumor bearing mammal to conform or approach the daily prolactin peak for healthy members of the same species and sex of said mammal. Claim 22 is drawn to the method of claim 1, wherein administering the prolactin enhancer adjusts the daily prolactin peak of the tumor bearing mammal to peak at night.

Claim 3 of US Patent No. 5,792,748 is drawn to a method for inhibiting neoplastic growth in a mammal in need of such treatment comprising administering prolactin at a predetermined time during a 24-hr period. Claim 8 of US Patent No. 5,792,748 is drawn to the method of claim 3, wherein said administration adjusts the prolactin profile of said mammal to conform to or approach the standard profile of a healthy mammal of the same species and sex. Claim 13 of US Patent No. 5,792,748 is drawn to the method of

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claim 8 wherein the mammal is a human. Claim 19 of US Patent No. 5,792,748 is drawn to the method of claim 13, wherein said neoplasm is a member selected from the group consisting of sarcomas, fibrosarcoms, carcinomas, glioblastomas, and melanomas.

Werning et al teaches that combining photodynamic therapy (exposing said contacted tumor cells to light) with metoclopramide increases the percentage of tumor regression versus photodynamic therapy alone (see abstract). Metoclopramide, as evidenced by Molitch, is a prolactin enhancer.

Cincotta et al teaches that 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride is a photodynamic agent which activates solid tumors (page 1257, in particular) and that photodynamic therapy with 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride in mice resulted in direct tumor cell killing (see abstract, in particular).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to optimize the claimed invention of Cincatta et al (US Patent 5,792,748) so as to include photodynamic therapy. One would have been motivated to do so because it was previously taught in the art that combining photodynamic therapy with the administration of a prolactin enhancer resulted in the increased regression of tumors versus prolactin enhancer therapy alone. Furthermore, the teachings of Cincatta et al (Cancer Research, 1994) promote the use of highly selective photosensitizers, like 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride, for optimizing cell killing with photodynamic therapy. Thus, clearly, the

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combined teachings suggest to one of skill in the art a reasonable expectation of success in arresting the growth of or eradicating tumors by combining photodynamic therapy with the administration of prolactin enhancers.

Claims 1-3, 6, 10, 15, 20 and 21 are directed to an invention not patentably distinct from claims 3, 8, 13, and 19 of commonly assigned U.S. Patent No. 5,792,748, for the reasons above.

Commonly assigned U.S. Patent No. 5,792,748, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the Examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude the rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

Claims 1-4, 10, 15, 20 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 13, 28, and

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30 of U.S. Patent No. 6,071,914 in view of Lin (Cancer Cells, 1991, 3(11)) and Cincotta et al (Cancer Research, 1994, 54:1249-1258). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-3, 10, 15, 20 and 21 are described above. Claim 4 is drawn to the method of claim 3 wherein said prolactin enhancer is melatonin or a pharmaceutically acceptable salt thereof.

Claim 1 of U.S. Patent 6,071,914 is drawn to a method for treating a patient suffering from a neoplasm comprising the steps of: comparing the blood prolactin level of said patient at each of a plurality of spaced apart time points during a 24-hour period to the corresponding prolactin level of a baseline prolactin level of healthy humans of the same sex as said patient; and adjusting the prolactin level of said patient to cause the patient's prolactin profile approach or conform to the baseline prolactin profile by administering a prolactin reducer to said mammal at a predetermined time, thereby inhibiting growth of said neoplasm in said human. Claim 12 of U.S. Patent 6,071,914 is drawn to the method of claim 1, further comprising administering a prolactin enhancer to said patient. Claim 13 of U.S. Patent 6,071,914 is drawn to the method of claim 12, wherein said prolactin reducer is bromocriptine and said prolactin enhancer is melatonin. Claim 18 of U.S. Patent 6,071,914 is drawn to a method for treating a patient suffering from a neoplasm comprising adjusting the prolactin level of said patient to cause the patient's prolactin profile to approach or conform to the baseline prolactin profile by administering a prolactin reducer to said patient at a predetermined time, thereby inhibiting the growth of said neoplasm in said human. Claim 28 of U.S. Patent

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6,071,914 is drawn to the method of claim 18, wherein said method further comprises administering a prolactin enhancer to said patient. Claim 30 of U.S. Patent 6,071,914 is drawn to the method of claim 28, wherein said prolactin reducer is bromocriptine and said prolactin enhancer is melatonin.

Lin summarizes the state of the art of photodynamic therapy of malignant tumors, including the use of selective photosensitizers like phthalocyanine dyes and iodinated benzophenothiazine (pages 439-439, in particular).

Cincotta et al (Cancer Research) also teaches that photodynamic therapy is a promising new approach for the selective eradication of neoplastic tissue and further teaches the successful use of 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride. A benzophenoxazine analog, as a photosensitizing agent and teaches a method of treating tumors in a mammal with said photosensitizing agent and that photodynamic therapy of EMT-6 tumors in mice with said photosensitizing agent resulted in direct tumor cell killing.

In the absence of unexpected results, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine photodynamic therapy with the patented invention of adjusting prolactin levels since each of these methods had been taught by the prior art to successfully eradicate neoplasm. Clearly, the instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the very same purpose since the idea of combining them flows logically from

their having been individually taught in the prior art. Thus, one of ordinary skill in the art would have reasonably expected to successfully treat tumors using both methods combined.

Claims 1-4, 10, 15, 20 and 21 are directed to an invention not patentably distinct from claims 12, 13, 28, and 30 of commonly assigned U.S. Patent No. 6,071,914, for the reasons above.

Commonly assigned U.S. Patent No6,071,914, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the Examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude the rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being obvious over Cincotta et al (US Patent 5,792,748; filed 6/7/95) in view of Werning et al (Arch. Ontolaryngol. Head Neck Surg., 7/95, 121:783-789) and Cincotta et al (Cancer Research, 1994, 54:1249-1258), as evidenced by Molitch (Endocrinol. Metab. Clin. North Am., 1992, 21(4):abstract).

Claims 1-4, 6, 10, 15, 20 and 21 are described above. Claim 5 is drawn to the method of claim 4 wherein said melatonin or a pharmaceutically acceptable salt thereof is administered in an amount within the range of about 0.5 to about 20 mg/person/day. Claim 7 is drawn to the method of claim 2 wherein said prolactin enhancer is administered at a time between about 19:00 and 1:00. Claim 8 is drawn to the method of claim 4 wherein said prolactin enhancer is administered at a time between about 19:00 and 1:00. Claim 8 is drawn to the method of claim 4 wherein said prolactin

enhancer is administered at a time between about 19:00 and 1:00. Claim 11 is drawn to the method of claim 4 wherein said photosensitizer is selected from the group consisting of porphyrin dyes, phthalocyanine dyes, cyanine dyes, benzophenoxazine analogs, and pharmaceutically acceptable salts thereof. Claim 12 is drawn to the method of claim 5 wherein said photosensitizer is selected from the group consisting of porphyrin dyes. phthalocyanine dyes, cyanine dyes, benzophenoxazine analogs, and pharmaceutically acceptable salts thereof. Claim 13 is drawn to the method of claim 7 wherein said photosensitizer is selected from the group consisting of porphyrin dyes, phthalocyanine dyes, cyanine dyes, benzophenoxazine analogs, and pharmaceutically acceptable salts thereof. Claim 14 is drawn to the method of claim 8 wherein said photosensitizer is selected from the group consisting of porphyrin dyes, phthalocyanine dyes, cyanine dyes, benzophenoxazine analogs, and pharmaceutically acceptable salts thereof. Claim 16 is drawn to the method of claim 11 wherein said benzophenoxazine analog is a member selected from the group consisting of 5-ethylamino-9-diethylamino-2iodobenzo[a]phenothiazinium chloride and 5-ethylamino-9-diethylaminobenzo[a]phenothiazinium chloride. Claim 17 is drawn to the method of claim 12 wherein said benzophenoxazine analog is a member selected from the group consisting of 5ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride and 5-ethylamino-9diethylamino-benzo[a]phenothiazinium chloride. Claim 18 is drawn to the method of claim 13 wherein said benzophenoxazine analog is a member selected from the group consisting of 5-ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride and 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride. Claim 19 is drawn to

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the method of claim 14 wherein said benzophenoxazine analog is a member selected from the group consisting of 5-ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride and 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride.

Cincotta et al (US Patent 5,792,748; filed 6/7/95) teaches a method for inhibiting the growth of neoplasm in a human mammal having a prolactin profile comprising comparing the prolactin profile of the afflicted mammal to a standard prolactin profile for healthy mammals of the same species and sex and adjusting the prolactin profile of the afflicted mammal to conform to or approach the standard prolactin profile for a mammal of the same species and sex of the afflicted mammal, thereby inhibiting neoplastic growth (abstract, in particular). US Patent 4,792,748 further teaches administering a prolactin enhancer wherein said prolactin enhancer includes prolactin as well as substances which increase circulating prolactin levels, such as melatonin (column 8 line 4, in particular). US Patent 4,792,748 further teaches that melatonin is administered in an amount within the range of about 0.5 to about 20mg/person/day (column 8 lines 48-50, in particular). US Patent 5,792,748 further teaches administration of the enhancer before or at bedtime, which reads on a time between 19:00 and 1:00 (column 9 line 50, in particular).

Werning et al teaches that combining photodynamic therapy with the metoclopramide increases the percentage of tumor regression versus photodynamic therapy alone (abstract, in particular). Metoclopramide, as evidenced by Molitch, is a prolactin enhancer.

Cincotta et al teaches that 5-ethylamino-9-diethylamiono-benzo[a]phenothiazinium chloride, a benzophenoxazine analog, is a unique photodynamic agent which inactivates solid tumors (page 1257, in particular) and that photodynamic therapy of EMT-6 tumors in mice with the 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride resulted in direct tumor killing (abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to optimize the claimed invention of Cincatta et al (US Patent 5,792,748) so as to include photodynamic therapy. One would have been motivated to do so because it was previously taught in the art that the combination of photodynamic therapy with administration of a prolactin enhancer results in the increased regression of tumors versus photodynamic therapy alone. Furthermore, the teachings of Cincatta et al (Cancer Research, 1994) promote the use of highly selective photosensitizers, such as 5-ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride and 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride, for optimizing cell killing in photodynamic therapy. Thus, clearly, the combined teachings suggest to one skilled in the art a reasonable expectation of success in arresting the growth of or eradicating tumors by combining photodynamic therapy with the administration of a prolactin enhancer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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